

Options Paper:

Data Submitter Rights for Data Submitted in Support of Tolerance Actions

As part of the Food Quality Protection Act of 1996, Congress amended section 408(i) of the Federal Food, Drug, and Cosmetic Act to address exclusive use and compensation rights for data submitted to EPA in support of tolerance and tolerance exemption actions. The Agency is currently evaluating how to implement this new provision and is seeking public comment.

I. Background

EPA is responsible under section 3 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) for registering pesticide products on the basis of scientific data or other information adequate to show that, among other things, the products will not pose unreasonable adverse effects on the environment. When applying for, or maintaining a registration, EPA may require that applicants and registrants submit data to the Agency to assess whether a pesticide should be registered or continue to be registered. Persons wanting to obtain or maintain a registration for a pesticide product must submit an application package consisting of information relating to the identity and composition of the product, and supporting data or a citation to supporting data.

FIFRA section 3(c)(1)(F) extends exclusive use or compensation rights to persons (“original data submitters”) who submit proprietary data, in support of an application for registration, reregistration, or experimental use permit, or to maintain an existing registration. Applicants who cite supporting data previously submitted to the agency by the original data submitter, must certify that an offer of compensation has been made to the original data submitter or that the submitter has granted permission to cite data. In the case of “exclusive use” data, the

applicant must obtain the permission of the original data submitter and certify with the Agency that the applicant has obtained written authorization from the original data submitter. If an applicant or registrant fails to comply with these requirements, the application/registration is subject to denial or cancellation.

Since FIFRA places an obligation on the Agency to ensure that the original data submitter is offered compensation for the use of data, a Pesticide Data Submitters List was developed to assist applicants in fulfilling their obligation. The Data Submitters List is a compilation of names and addresses of original data submitters who wish to be notified and offered compensation for use of their data. The Data Submitters List is available via the Internet at <http://www.epa.gov/opppmsd1/DataSubmittersList>.

For pesticides that may remain in or on food or animal feed, a maximum residue level (tolerance) must be established. In considering a tolerance action, EPA reviews certain types of data on a pesticide to determine if residue limits will be safe. Prior to passage of the Food Quality Protection Act (FQPA) of 1996, the Federal Food, Drug, and Cosmetic Act (FFDCA) did not contain a data compensation and exclusive rights provision. Nonetheless, EPA has consistently taken the position that data submitted to support a tolerance or tolerance exemption are entitled to exclusive use or compensation if the data otherwise meet the requirements of section 3 of FIFRA. Specifically, the data must be submitted in support of a registration or reregistration action or must otherwise be submitted to support or maintain registration. Because most “tolerance-related” data are submitted to support registration actions, these data generally are compensable under FIFRA.

II. Amendments to the Law

In 1996, Congress amended the FFDCA to add a new section 408(i) that explicitly

addresses compensation and exclusive use rights for data submitted to support tolerances and tolerance exemption. Congress provided that such data are compensable “to the same extent” provided in section 3 of FIFRA. However, the statute gives no further guidance as to whether this provision is simply intended to codify EPA’s current practice, or whether Congress intended to expand data compensation rights to those data that currently do not enjoy compensation or exclusive use rights. The pertinent part of the statutory language reads:

408(i) Confidentiality and Use of Data. –

(1) General rule.- Data and information that are or have been submitted to the Administrator under this section or section 409 in support of a tolerance or an exemption from a tolerance shall be entitled to confidential treatment for reasons of business confidentiality and to exclusive use and data compensation to the same extent provided by sections 3 and 10 of the Federal Insecticide, Fungicide, and Rodenticide Act.

EPA may receive data submitted in support of tolerance or tolerance exemption actions that are not submitted to support FIFRA registration actions. Specifically, data submitted by inert manufacturers and data submitted by persons petitioning for the issuance of a tolerance for a pesticide on imported food are generally not submitted in connection with any action under FIFRA. Under FIFRA such data would not, therefore, qualify for exclusive use or compensation status.

While the statute is silent on this matter, the legislative history does suggest that Congress wanted to provide protections for data submitted by inert manufacturers. Since most data submitted by inert manufacturers is not subject to protection under section 3 of FIFRA (because the data generally are not submitted in connection with a registration action), the legislative

history may indicate that Congress did intend to expand compensation and exclusive use rights. However, given the language of section 408(I), it is unclear to EPA precisely how such rights would be expanded. If the language “to the same extent provided by section 3” truly incorporates all the provisions of section 3, data rights could not be expanded beyond current practice because section 3 requires that the data be connected to a FIFRA registration action. Thus, if Congress did intend to expand data rights by enacting new 408(I), it may have intended the Agency to use section 3 of FIFRA merely as a guidepost for developing protections for tolerance related data.

III. Preliminary Options for Implementing Section 408(i)

EPA specifically solicits comments addressing the Agency’s implementation of the provisions of section 408(i) of FFDCA that relate to exclusive use and compensation rights. Three preliminary options are presented for consideration. The options represent different interpretations of the potential scope of the new provision focusing on who they might apply to. EPA also encourages commenters to submit comments on other interpretations of the new language and suggest procedures for implementing whatever option the commentor prefers.

EPA believes the new section 408(i) of FFDCA may provide the Agency with the flexibility to develop one or more possible implementation schemes. After consideration of the comments received, the Office of Pesticide Programs will develop a proposal for implementing the data compensation and exclusive use provisions for data submitted to EPA under section 408(I).

A. Option 1: Only Registrants and Applicants for Registration

One approach to implementing section 408(i) would extend data compensation and

exclusive use rights (data rights) only to those persons who submit data in support of tolerances or exemptions from tolerances that also meet all the conditions necessary to obtain such rights as set forth in section 3 of FIFRA. This option would read section 408(i) as Congressional ratification of the Agency's current treatment of "tolerance" related data. Therefore, under this option, data rights under section 408(i) would only extend to those persons who qualify as "applicants" under FIFRA for a current registration or reregistration action (See section 3(c)(1)(F) of FIFRA).

B. Option 2: Any Person Who Submits Data Related to Current Registration/reregistration Action

This reading of section 408(I), as in option 1, would extend data rights to those persons who submit data in support of tolerances or exemptions from tolerances that also meet all the conditions necessary to obtain such rights as set forth in section 3 of FIFRA, with the exception that the submitter would not have to be an "applicant or registrant" as section 3(c)(1)(F) of FIFRA provides. This option would give some meaning to the FQPA legislative history that indicates that Congress intended to offer protection to data submitted by inert ingredient manufacturers. It is unlikely, however, that this option would protect much data submitted by inert manufacturers, since such data are rarely submitted for the specific purposes identified in FIFRA section 3 (registration, reregistration, etc.).

C. Option 3: Any Person Without Regard to Whether Data Relate to Current Registration or Reregistration

This reading of section 408(i) would extend data compensation and exclusive use rights to persons who submit data and who would otherwise qualify for data rights under both options 1

and 2 above. However, this option would also extend rights to data submitters without regard to whether the data submitted relates to any current registration or reregistration action or whether the data submitter is a pesticide registrant. Protections would only be linked to the issuance of tolerances and tolerance exemptions. This approach would likely extend protection to data submitted by manufacturers of inert ingredients and persons submitting data in support of a tolerance or exemption to a tolerance for pesticide chemical residues on imported food. Because these individuals generally do not submit data in connection with pesticide registration activities under FIFRA, options 1 and 2 above would likely not provide the measure of data protection provided by this option.

Commenters should note that because section 408(i) by its terms is not limited to “inerts” data, any expansion of rights created by 408(i) may apply to data on active ingredients in a similar manner. Further, it should be noted that all three options would be implemented in connection with the FIFRA registration/reregistration process. Because the FFDCA does not provide a licensing scheme for levying data requirements on all persons who market products that may benefit from the issuance of tolerances or tolerance exemptions, EPA believes Congress intended to utilize the existing FIFRA process to ensure protection of the rights identified in FFDCA section 408(i).

A brief outline of these options was presented to the Pesticide Program Dialog Committee (PPDC) in January 1999. The PPDC is an advisory committee organized under the Federal Advisory Committee Act. Currently the PPDC is comprised of approximately 27 members from the pesticide industry, user, and commodity groups; Federal and State governments; consumer and environmental/public interest groups, including representatives from the general public; academia; and, public health organizations. The PPDC provides advice and guidance to the

Office of Pesticide Programs regarding pesticide regulatory, policy, and implementation issues.

Informally, several PPDC members expressed an interest in the development and implementation of the broadest interpretation of the statutory language.

IV. Submitting Comments

EPA specifically solicits public comments on the options described in this paper. However, comments submitted on other interpretations of the new language will also be considered. EPA asks commentors to also include suggested procedures for implementing whatever option the commentor prefers. To date, the Agency has already received a position paper from The Council For Advanced Agricultural Formulations, Inc., an association representing certain manufacturers of inert ingredients in pesticide products, setting forth a proposed implementation scheme for this new provision that is similar to Option 3.